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| ART UNIT | PAPER NUMBER |
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1624

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070 976

Applicant(s)

Pfleiderer

Examiner

J.M. Ford

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on Aug 15, 2003
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-- 9 and 11--14 is/are pending in the application.
- Of the above claim(s) 2-- 9 and 11--14 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-- 6 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: German 199 74 767.5

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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Applicant's response of August 15, 2003, is noted.

The claims in the application are claims 1—9 and 11—14.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph.

In R1 and R2 together a ring is found, said ring is said to be substituted with a radical. What is the radical?

This is a compound claim. What compound(s) is/are being claimed?

Claim 2 is rejected for the reasons claim 1 is/was rejected.

Aryl means a carbocyclic aryl. Applicants are entitled to be their own lexicographer up to the point that they define a letter or term to mean something other than its pre-defined IUPAC meaning.

It becomes necessary to separate carbocyclic aryl from heterocyclic aryl to determine patentability, as heteroaryl is such a large term it could not be supported.

Claim 2 is, therefore, also rejected under 35 U.S.C. 112, 4th paragraph, for lack of antecedent basis, as heteroaryl appears for the first time in claim 2. Therefore, claim 2 is not properly dependent on claim 1.

Heteroaryl, in claim 2, near the end of the claim, indicates "at least one hetero atom". This type of "open" language does not meet 35 U.S.C. 112, 1st or 2nd paragraph.

Claiming is alternative. One at a time compound.

A compound selected from the group consisting of:

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The unlimited mixtures at the end of claims 1—4 breaks that requirement by claiming mixtures. See Ex parte Tinsley, U.S. Patent file 3,311,643, Paper # 20, page 3 of 5 pages Decision. 35 U.S.C. 112, 2nd paragraph.

In claim 3, it would be improper to confuse the meaning of aryl to include thienyl, furyl and pyridine. Thiophene, furan, and pyridine ^{are} ~~are~~ aromatic, but not aryl, which is required to be carbocyclic to divide the subject matter between what is allowable, and what is not. We need to keep that distinction clear, between carbocyclic aryl and heterocyclic aryl. It is possible to confuse the two to the point patentable distinction could not be made. We need to be able to allow thiophene, when the art shows benzene. We need to be able to cling to that distinction to resolve Interferences.

The expression in claim 3 that aryl is heterocyclic causes claim 3 to be rejected under 35 U.S.C. 103, 4th paragraph.

Claims 2—6 are rejected as being dependent on a rejected claim.

Claims 1—4 contain rejected terms. Mixtures are a different invention.

Heteroaryl in claim 2 will have to be exactly defined, see claim 3, and removed from being included in aryl.

Compounds of the type claimed here are classified as heterocyclic in classes 544 and 546 and 549 and 540. Mixtures are in class 252. Mixtures will ultimately have to be removed here, as a different invention.

Claim 7 is "open" by the use of "at least". Therefore, not compliant with 35 U.S.C. 112, 1st or 2nd paragraphs.

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Claim 8 needs be limited to one use. It is not believable, on its face, that any one compound could have all of those uses. Even if it were, it would require undue experimentation to determine what host – dosage relationship would produce what result. Many of the uses listed are so sensitive that they do not have an established regimen of treatment.

This is a 371 application. Restriction in 371 applications is controlled by 37 CFR 1.475. Rule 475 makes it clear that once a compound claim is determined to have allowable language that applicants are entitled to have, at most, one use of those compounds and one method of making those compounds; provided the claims are all of the same scope.

Therefore, claims 7, 8, 9, 11, 12, 13 and 14 continue withdrawn, at this point.

Applicants may not petition the restriction requirement, at this point, as it has not been made Final. See 37 CFR 1.144.

Nothing has been made Final at this point. This is a work in progress.

Summary

Claims 1—6 are rejected under 35 U.S.C. 112 (various sub paragraphs).

Claims 7—9 and 11—14 stand withdrawn.

It is suggested that applicants say aryl or heteroaryl and then define aryl and heteroaryl in the claim 1.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph, as the claim is not clearly directed to the elected invention, solely, as noted above.

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Hydrocarbyl is not limited from infinity in its hydrocarbon length. We do not know if it is branched or unsaturated. Is it cyclic?

The aryl, heteroaryl or heterocyclic in R and Y do not tell the reader what is intended by aryl, heteroaryl, heterocycle, or the heterocyclic of Y. Where are the hetero atoms located in the unknown ring?

Judge Smith found multiple different definitions for aryl in *In re Sus*, 134 USPQ 301, and listed some of the different definitions for aryl in the footnotes of that case. Therefore, applicants need to tell us what they intend by aryl, but not that it is heteroaryl.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

Heteroaryl is entirely inadequate. Where are the heteroatoms in the ring? How many hetero atoms are present in the ring. Applicants are placing specific conception with the reader. Not a fair burden in return for applicants getting a 17/20 year monopoly on compounds, not yet made. Adjacent O/S; O/O or S/S combinations have not been made, as they are notoriously unstable. What is the source of the starting materials? These are compound claims that carry with it the right to exclude others. Applicants should not be permitted to pre-empt

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others from future endeavors, when they, the public, finally do make the compounds included in the huge unknown numbered claimed in genus: heteroaryl.

Claim 1, is therefore, also rejected under 35 U.S.C. 112, 1st paragraph, as the specification does not contain adequate representative exemplification for the breadth claimed.

The USPTO only recognizes: C, N, O, S, Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl.

Heteroaryl is not just a substituent; it is whole body of art, larger than the nucleus claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

What the heteroaryl is may often control the classification and search of the molecule.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim:

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Note United Carbon C. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim; this ground finds its basis in the second paragraph of section 112; second is that language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from the first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heteroaryl concept is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role of the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you

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(the public) find that it works, I claim it, is not a proper basis for patentability;

In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heteroaryl rings possible is wide open to staggering possibilities.

Applicants place too much conception with reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines.

Where are the starting materials in the specification?

Specific conception of what the intended heteroaryl ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heteroaryl applied by applicant, has no idea where the hetero atoms are in this unknown ring.

What are the hetero atoms? What size is the ring in heteroaryl?

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heteroaryl ring, in question.

It becomes necessary for applicants to indicate in the claims what they mean by heteroaryl. Heteroaryl, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those

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patents as hetero rings. What applicants intend need be found in the claim.

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming and support in the specification for the variables sought.

This rests specific conception with the reader.

What exactly is intended, and where is that supported in the specification. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quite large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicant's breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they demonstrated as a specific fact.

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The heteroaryl expression in claim 1 et seq., is not acceptable, as it does not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know compound is being claimed.

The claims measure the invention, *United Carbon Co. vs. Binney & Smith Co.*, 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

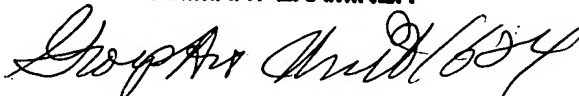
The U.S. Court of claims held to this standard in *Lockhead Aircraft Corp. vs. United States*, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "That invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 U.S.P.Q. 11, at 15.

J. M. Ford:jmr

October 02, 2003


JOHN M. FORD
PRIMARY EXAMINER


Gayle Ann Smith